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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/607,434	06/26/2003	Mark P. Anstadt	034448-007	5213

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EXAMINER
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OROPEZA, FRANCES P

ART UNIT	PAPER NUMBER
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3766

DATE MAILED: 09/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/607,434	<b>Applicant(s)</b> ANSTADT ET AL.	
	<b>Examiner</b> Frances P. Oropeza	<b>Art Unit</b> 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 6/21/06 (Amendment and RCE).
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 131, 133, 150-155 and 243 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 131, 133, 150-155 and 243 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>6/21/06</u> . | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

***Request for Continued Examination***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. The Applicant's submission filed on 6/21/06 has been entered.

***Restriction***

2. Claim 131 has been amended and is similar to claim 243, hence restriction of 4/11/06 is withdrawn and claims 131, 133 and 150-155 and 243 are being prosecuted.

***Response***

3. The Applicant at least amended independent claim 131 in the response filed 6/21/06, hence the rejection of record is withdrawn and a new rejection established in the subsequent paragraphs.

***Claim Rejections - 35 USC § 102***

4. Claims 131, 133, 150-153 and 155 are rejected under 35 U.S.C. 102(b) as being anticipated by Easterbrook et al. (US 6238334). Easterbrook et al. disclose a process for assisting the function of a heart, comprising a single continuous cavity of variable volume extending circumferentially completely around the outer wall of the heart (14), and a controller

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importing the electrocardiogram signal into a pump with an accepted fluid pressure signal for use in an accepted controlling algorithm, accepted to be programmed by the physician (abstract; figure 1, 27; col. 5 @ 16-24; col. 5 @ 52 – col. 6 @ 26; col. 8 @ 13-34; col. 12 @ 56-62; col. 14 @ 50 – col. 15 @ 14).

5. Claims 131, 133, 150-153 and 155 are rejected under 35 U.S.C. 102(b) as being anticipated by Tsitlik et al. (US 5971910). Tsitlik et al. disclose a apparatus and method for assisting the function of a heart, comprising a single continuous cavity of variable volume extending circumferentially completely around the outer wall of the heart (36), and a controller importing the electrocardiogram signal into a vacuum pump with an accepted fluid pressure signal for use in an accepted controlling algorithm, accepted to be programmed by the physician (abstract; figure 1; col. 4 @ 47 – col. 5 @ 15; col. 5 @ 44-67; col. 11 @ 22-24).

6. Claims 131, 133, 150-153, 155 and 243 are rejected under 35 U.S.C. 102(b) as being anticipated by Grooters (US 5131905). Grooters discloses a process for augmenting cardiac contractions, comprising a single continuous cavity of variable volume extending circumferentially completely around the outer wall of the heart (33) with two chambers (34 and 36, or 34 and 38 – depending on the needed assistance), and a controller importing the electrocardiogram signal into a pump with an accepted fluid pressure signal for use in an accepted controlling algorithm, accepted to be programmed by the physician (abstract; figure 3; col. 1 @ 49-52; col. 1 @ 66- col. 2 @ 17; col. 2 @ 48 – col. 3 @ 7; col. 3 @ 48-57).

***Claim Rejections - 35 USC § 103***

7. Claim 154 is rejected under 35 U.S.C. 103(a) as being unpatentable over Grooters (US 5713954) in view of Kung et al. (US 6626821). As discussed in paragraph 6 of this action, Grooters discloses the claimed invention except for the controller using the drive fluid flow rate.

Kung et al. flow balancing in a ventricular assist device using a controller to change volumes within the single continuous cavity of variable volume based on drive fluid flow rate for the purpose of varying the ventricular ejection volume. It would have been obvious to one having ordinary skill in the art at the time of the invention to have the controller effect changes in the volume within the single continuous cavity of variable volume based on the drive fluid flow rate in the Grooters system in order to properly adjust the ventricular ejection volume to establish the right and left ejection pressures appropriate for the patient (col. 3 @ 58061 col. 5 @ 17-28).

***Information Disclosure Statement***

8. The information disclosure statements do not appear to comply with the guidelines set forth in MPEP 2004 regarding the elimination of clearly irrelevant art and marginally cumulative information because one reference is an approximately 700 page book and another reference is a 340 page book . However, compliance with these guidelines is not mandatory. Furthermore, 37 CFR 1.97 and 1.98 do not require that the information be material; rather, they allow for submission of information regardless of its pertinence to the claimed invention. Also, there is no requirement to explain the materiality of the submitted references.

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9. However, burying of a clearly relevant reference in a lengthy reference may not comply with the Applicant's duty of disclosure. Applicant is advised that the MPEP states the following with respect to large information disclosure statements:

Although a concise explanation of the relevance of information is not required for English language information, applicants are encouraged to provide a concise explanation of why the English-language information is being submitted. Concise explanations (especially those that point out the relevant pages and lines) are helpful to the Office, particularly where documents are lengthy and complex and applicant is aware of a section that is highly relevant to patentability or where a large number of documents are submitted and applicant is aware that one or more is highly relevant to patentability. MPEP § 609.04(a)(III).

This statement is in accord with dicta from *Molins PLC v. Textron, Inc.*, 48 F.3d 1172 (Fed. Cir. 1995), stating that forcing the Examiner to find "a needle in a haystack" is "probative of bad faith." *Id.* at 1888. This case presented a situation where the disclosure was in excess of 700 pages and contained more than fifty references. *Id.* 1888.

10. The MPEP provides more support for this position. In a subsection entitled "Aids to Compliance With Duty of Disclosure," item thirteen states:

It is desirable to avoid the submission of long lists of documents if it can be avoided. Eliminate clearly irrelevant information and marginally pertinent cumulative information. If a long list is submitted, highlight those documents which have been specifically brought to Applicant's attention and/or are known to be of the most significance. See *Penn Yan Boats, Inc. v. Sea Lark Boats, Inc.*, 359 F.Supp 948 (S.D. Fla. 1972) *aff'd* 479 F.2d 1338 (5<sup>th</sup> Cir 1974). MPEP § 2004.

11. Therefore, it is recommended that if any information that has been cited by applicants in the above referenced information disclosure statements is known to be material for patentability as defined by 37 CFR 1.56, Applicant should present a concise statement as to the relevance of that/those particular documents therein cited.

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*Statutory Basis*


12. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

*Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fran Oropeza whose telephone number is (571) 272-4953. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571) 272-6996. The fax phone numbers for the organization where this application or proceeding is assigned is (571) 273-8300 for regular communication and for After Final communications.

Frances P. Oropeza  
Patent Examiner  
Art Unit 3766

FP  
8/29/06

  
Robert E. Pezzuto  
Supervisory Patent Examiner  
Art Unit 3766